

REMARKS

Status of Claims

Claims 7-11 are pending in the application. Claims 7-11 are rejected.

Response To Double Patenting Rejection

Claims 7-11 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,936,594 to Morishita et al. for the reasons of record.

In addition, the Office Action appears to assert that Applicants' arguments are not persuasive because although "peripheral" is not "central" with regard to the nervous system, the peripheral circulation is not the peripheral nervous tissue and is circulation that is not the cardiac circulation. The Office Action provides a definition of peripheral vascular disease from MedicineNet.com to support this position.

Applicants respectfully disagree and traverse the rejection as follows.

Applicants note that peripheral circulation is different from cerebral circulation.

First, peripheral vascular disease refers to diseases of blood vessels outside the heart and brain.¹

Second, there is a clear delineation in the medical art between cerebral circulation and peripheral circulation. Cerebral circulation is involved with the supply of blood to the brain, and

¹ Peripheral Vascular Disease, <http://www.americanheart.org/presenter.jhtml?identifier=4692>. A copy is submitted herewith. In accordance with M.P.E.P. 609.05(c), the documents cited herein in support of Applicants' remarks are being submitted as evidence directed to an issue raised in the Official Action, and no fee pursuant to 37 C.F.R. 1.97 or 1.98, or citation on a FORM PTO/SB/08A & B is believed to be necessary.

cerebral vascular disease is due to problems with the cerebral circulation.² The large blood vessels supplying blood to the brain and spinal cord lie in the subarachnoid space.³ Disruptions in the brain's blood circulation to areas such as the subarachnoid space is known in the art to result in subarachnoid hemorrhage.⁴ Also, the subarachnoid space is active in the blood brain barrier system.

In contrast, peripheral circulation provides systemic blood supply to the lower extremities of the body, e.g., legs and feet, by the peripheral arteries and peripheral veins. As stated in the definition provided by the Examiner, “[p]eripheral vascular disease (PVD) affects the peripheral circulation...PVD comprises diseases of both peripheral arteries and peripheral veins...[i]ntermittent claudication [is] due to inadequate blood flow to the leg...while varicose veins and spider veins are examples of peripheral vein disease.” Also, for that matter, peripheral vascular disease is “the medical name given to a group of problems that causes poor circulation to the feet and legs.”⁵

Accordingly, reconsideration and withdrawal of the nonstatutory obviousness-type double patenting rejection is respectfully requested.

² See Cerebral Circulation: Encyclopedia of Neurological Disorders. A copy is submitted herewith. In accordance with M.P.E.P. 609.05(c), the documents cited herein in support of Applicants' remarks are being submitted as evidence directed to an issue raised in the Official Action, and no fee pursuant to 37 C.F.R. 1.97 or 1.98, or citation on a FORM PTO/SB/08A & B is believed to be necessary.

³ See <http://cancerweb.ncl.ac.uk/cgi-bin/omd?subarachnoid+space>.

⁴ See page 2 of Poor Cerebral Circulation.

⁵ See <http://www.epodiatriy.com/poor-circulation.htm>.

Response To Claim Rejections Under 35 U.S.C. § 102

Claims 7-9 and 11 remain rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,121,246 to Isner, for the reasons of record.

In addition, the Office Action asserts that Applicants' arguments are not persuasive because (1) HGF is recited in the claims of Isner as well as the specification, (2) Isner's claims teach gene therapy, and (3) Isner's complicated methods are limited to the examples and not the claims.

The Office Action further appears to assert that the subject matter of claim 10 is free of art, i.e., not taught by Isner or Morishita et al., because Applicants are the earliest inventors of such vectors.

Initially, Applicants note that pursuant to M.P.E.P. §2121.01, the disclosure in an alleged anticipating reference must provide an enabling disclosure of the desired subject matter, "mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation."

In this regard, Applicants note that Isner is directed to the treatment of ischemic tissue such as cerebrovascular ischemia, renal ischemia, pulmonary ischemia, limb ischemia, ischemic cardiomyopathy, and myocardial ischemia. (See Abstract of Isner). Isner discloses experimental data showing new blood vessel formation in ischemic muscle tissue by direct injection of a DNA encoding VEGF. Based on the experimental data of the VEGF gene, claim 1 of Isner is directed to a method for inducing the formation of new blood vessels in an ischemic muscle tissue by directly injecting into the tissue a DNA sequence encoding an angiogenic protein including VEGF and other various proteins. HGF is included in the other various

proteins recited in claim 1 of Isner. Accordingly, the claim of Isner recites the HGF gene, based on the assumption that HGF exhibits the same activity as that of VEGF.

However, Applicants note that it is known in the art that the administration of VEGF protein or VEGF gene induces edema, as evidenced by the following published literature articles submitted herewith. A copy of each is submitted herewith.

1. Baumgartner et al., Am. Intern. Med. 132: 880-884 (2000).
2. Kim et al., Exp. Mol. Med. 36 : 336-344 (2004).
3. Baumgartner et al., Circulation 97: 1114-1123 (1998).

In contrast, the administration of HGF in the present invention does not induce edema. In this regard, the presently claimed method provides unexpectedly superior results over Isner. Furthermore, Isner does not disclose administration of HGF gene to induce new blood vessel formation without inducing edema, nor does Isner provide sufficient disclosure to enable one of ordinary skill in the art to practice the presently claimed method.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

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